REMARKS

Claims 74-127, 129-131, 140, 158, 162, 164, 169-173 are pending, claims 128, 132-139, 141-157, 159-161, 163, 165-168 have been canceled, claims 169-173 are new, and claims 74, 115, 124, and 129 have been amended and find basis in the claims as originally filed and in the specification throughout (e.g., original claims 10, 14, and 34, and paragraphs 0019, 0021, 0024, 0042, and 0074). Accordingly, entry of the new claims and claim amendments will not introduce any prohibited new matter.

The Office rejected claims in the outstanding action as summarized hereafter:

i. Claims 74-108, 112-114, 124-128, 129-161 and 165-168 were rejected under 35 U.S.C. 112, second paragraph as being indefinite;

ii. Claims 74-84, 100-139 and 155-168 were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter; and

iii. Claims 74-168 were provisionally rejected for alleged obviousness-type double patenting over U.S. Application No. 10/933,611.

Applicant respectfully traverses these rejections for the reasons presented hereafter. The claims were amended to expedite prosecution, and Applicant respectfully asserts the outstanding rejections are inapplicable to the subject matter claimed herein.

Rejection for alleged non-statutory subject matter

Claims 74-84, 100-139 and 155-168 were rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter, and Applicant respectfully traverses the rejection in its entirety. The Office states on page 6 of the action that "the transformation of an article (i.e. the target nucleic acid into fragments) found in claims 85 and 140 is lacking in claims 74-84, 100-139 and 155-168." The Office on page 8 states that this rejection can be obviated by, "reciting an active step of performing mass spectrometry."

Amended independent claims 74, 115, 124 and 129 herein recite methods that incorporate the step of "generating mass signals for target nucleic acid fragments and reference nucleic acid fragments by mass spectrometry." Support for this feature can be found throughout the instant application (e.g. original claims 10, 14, and 34, and paragraphs 0019, 0021, 0024, 0042, and 0074).

Accordingly, the rejection under 35 U.S.C. 101 is moot in light of the claim amendments, and Applicant requests withdrawal of the rejection.

Rejections for alleged indefiniteness

Claims 74-108, 112-114, 124-128, 129-161 and 165-168 were rejected under 35 U.S.C. 112, second paragraph for alleged indefiniteness for being incomplete for omitting steps, see Office action at page 3, 2nd paragraph. The Office states on page 4 of the action that independent claims 74, 124 and 129 and their dependent claims have a "gap in the method" and further questions "how does one go from this list of possible sequences to the actual sequence?" The Office further suggests, "[t]he only means taught … was through the step of scoring the candidate sequences." The rejection respectfully is traversed in its entirety in view of the reasoning presented hereafter.

It is respectfully submitted that claim 74 is clear without a scoring step. The specification discusses using algorithms for various steps of the claimed method, one of which is uses the value of scores "to determine the sequence variation candidate that corresponds to the actual target nucleic acid sequence," paragraph 0027. One of skill in the art at the time of filing of the instant application can recognize several different ways to use algorithms in performing various steps of a method including the step of claims 74, 124 and 129 "whereby one or more sequence variations in the target nucleic acid are determined from the candidate sequence variations." For example, methods in the instant application calculate probability, determine whether a threshold has been achieved, and/or make calculations using a sensitivity and specificity level to determine the sequence, see for example paragraphs 0125 and 0447. The instant application notes that methods may include using a score "to determine the sequence variation candidate that corresponds to the actual target sequence," paragraph 0125. However, other algorithms may also be used. For example, paragraph 0043 discusses use of algorithms in general: "analysis of these signals by using algorithms that screen the signals to select only those that are likely to represent true sequence variations within the target nucleic acid." Therefore, one of skill

in the art understands the scope of claims 74, 124, and 129 "whereby one or more sequence variations in the target nucleic acid are determined from the candidate sequence variations."

Claims 124-128 were rejected under 35 U.S.C. 112, second paragraph for alleged indefiniteness. Claim 124 has been amended to more particularly point out the claimed subject matter. Specifically claim 124 has been amended to omit "amino acids", omit step "(d)," recite "(c)," and recite "a description of whether or not modified nucleotides are incorporated into all or part of the target sequence."

Claim 128 was rejected under 35 U.S.C. 112, second paragraph for alleged indefiniteness for lacking antecedent basis. The rejection is moot given the rejected claim is cancelled herein without prejudice or disclaimer.

Accordingly, the outstanding rejections for alleged indefiniteness are inapplicable to claims 74-108, 112-114, 124-128, 129-161 and 165-168 recited herein. Applicant therefore requests withdrawal of outstanding rejections under 35 U.S.C. 112, second paragraph.

Provisional double patenting rejection

Claims 74-168 were provisionally rejected for alleged obviousness-type double patenting over U.S. Patent Application No. 10/933,611 ("the '611 application"). Section 804 I(B)(1) in the MPEP states:

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

Applicant respectfully submits that these conditions are met and that withdrawal of this provisional rejection is warranted. The filing date of the instant application is November 26, 2003, which is earlier than the September 2, 2004 filing date of the '611 application. The '611 application also is rejected on other grounds. And in the instant application, the provisional non-statutory obviousness-type double patenting rejection will be the sole rejection remaining after the Office withdraws the rejections under 35 U.S.C. 112, second paragraph, and under 35 U.S.C. 101. Applicant

therefore respectfully requests withdrawl of the outstanding provisional rejection for alleged non-statutory obvousness-type double patenting.

CONCLUSIONS

Applicant respectfully submits all pending claims will be in condition for allowance upon entry of the amendments herein. Applicant respectfully solicits a prompt notification to this effect, and the Examiner is encouraged to contact the undersigned representative (contact information below) to promptly resolve any remaining issues or questions.

In the unlikely event a fee calculation document or other pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicant petitions for any required relief, including extensions of time, and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **50-3473**.

Respectfully submitted,

Date: May 7, 2009

By: /Tobey Tam/

Tobey Tam
Reg. No. 54484
Grant Anderson LLP
Customer No. 47328
Telephone: (858) 248-0178